

Claims

1. A method for characterizing an apparently healthy individual's risk profile of developing future diabetes or diabetic complications, comprising:
obtaining a level of a marker of systemic inflammation in the individual,
comparing the level of the marker to a predetermined value specific for the diagnosis of diabetes or diabetic complications, and
characterizing the individual's risk profile of developing a future diabetes based upon the level of the marker in comparison to the predetermined value.

2. The method of claim 1, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is a plurality of predetermined marker level ranges and said comparing step comprises determining in which of said predetermined marker level ranges said individual's level falls.

3. The method of claim 1, wherein the marker of systemic inflammation is selected from the group consisting of C-reactive protein and a cytokine.

4. The method of claim 1, wherein the marker of systemic inflammation is C-reactive protein.

5. The method of claim 4, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is about 0.30 mg/dL of blood or higher.

6. The method of claim 4, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is about 0.60 mg/dL of blood.

7. The method of claim 4, wherein the predetermined marker level is a plurality of predetermined marker level ranges, one of said plurality being below about 0.30 mg/dL of blood and another of said ranges being about 0.30 mg/dL blood, and wherein said comparing step comprises determining in which of said plurality of predetermined marker level ranges said individual's level falls.

8. The method of claim 1, wherein the marker of systemic inflammation is interleukin-6.

10017905-121401

9. The method of claim 8, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is about 1.39 pg/mL of blood or higher.

10. The method of claim 8, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is about 2.05 pg/mL of blood.

11. A method for characterizing an individual's risk profile of developing future diabetes or diabetic complications, comprising:

obtaining a level of a marker of systemic inflammation in the individual,

comparing the level of the marker of systemic inflammation to a first predetermined value specific for the diagnosis of diabetes or diabetic complications to establish a first risk value,

obtaining a level of a glycosylated hemoglobin in the individual,

comparing the level of the glycosylated hemoglobin to a second predetermined value specific for the diagnosis of diabetes or diabetic complications to establish a second risk value, and

characterizing the individual's risk profile of developing diabetes or diabetic complications based upon the combination of the first risk value and the second risk value, wherein the combination of the first risk value and second risk value establishes a third risk value different from said first and second risk values.

12. The method of claim 11, wherein the first predetermined value specific for the diagnosis of diabetes or diabetic complications is a first plurality of predetermined marker level ranges and said comparing step comprises determining in which of said first predetermined marker level ranges said individual's level falls.

13. The method of claim 11, wherein the marker of systemic inflammation is selected from the group consisting of C-reactive protein and a cytokine.

14. The method of claim 11, wherein the marker of systemic inflammation is C-reactive protein.

15. The method of claim 14, wherein the first predetermined value specific for the diagnosis of diabetes or diabetic complications is about 0.30 mg/dL of blood or higher.

10017905-121401

16. The method of claim 14, wherein the first predetermined value specific for the diagnosis of diabetes or diabetic complications is about 0.60 mg/dL of blood.

17. The method of claim 14, wherein the predetermined marker level is a plurality of predetermined marker level ranges, one of said plurality being below about 0.30 mg/dL of blood and another of said ranges being about 0.30 mg/dL blood, and wherein said comparing step comprises determining in which of said plurality of predetermined marker level ranges said individual's level falls.

18. The method of claim 11, wherein the marker of systemic inflammation is interleukin-6.

19. The method of claim 18, wherein the first predetermined value specific for the diagnosis of diabetes or diabetic complications is about 1.39 pg/mL of blood or higher.

20. The method of claim 18, wherein the first predetermined value specific for the diagnosis of diabetes or diabetic complications is about 2.05 pg/mL of blood.

21. A method for evaluating the likelihood that an individual will benefit from treatment with an agent for reducing the risk of diabetes or reducing the risk of diabetic complications, the agent selected from the group consisting of insulin, a hypoglycemic agent, an anti-inflammatory agent, a lipid lowering agent, a calcium channel blocker, a beta-adrenergic receptor blocker, a cyclooxygenase-2 inhibitor, and an angiotensin system inhibitor, comprising:

obtaining a level of a marker of systemic inflammation in the individual, and
comparing the level of the marker to a predetermined value specific for the diagnosis of diabetes or diabetic complications, wherein the level of the marker of systemic inflammation in comparison to the predetermined value is indicative of whether the individual will benefit from treatment with said agents.

22. The method of claim 21, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is a plurality of predetermined marker level ranges and said comparing step comprises determining in which of said predetermined marker level ranges said individuals level falls.

10017905.121401

23. The method of claim 21, wherein the marker of systemic inflammation is selected from the group consisting of C-reactive protein and a cytokine.

24. The method of claim 21, wherein the marker of systemic inflammation is C-reactive protein.

25. The method of claim 24, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is about 0.30 mg/dL of blood or higher.

26. The method of claim 24, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is about 0.60 mg/dL of blood or higher.

27. The method of claim 24, wherein the predetermined marker level is a plurality of predetermined marker level ranges, one of said plurality being below about 0.30 mg/dL of blood and another of said ranges being about 0.30 mg/dL blood, and wherein said comparing step comprises determining in which of said plurality of predetermined marker level ranges said individual's level falls.

28. The method of claim 21, wherein the marker of systemic inflammation is interleukin-6.

29. The method of claim 28, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is about 1.39 pg/mL of blood or higher.

30. The method of claim 28, wherein the predetermined value specific for the diagnosis of diabetes or diabetic complications is about 2.05 pg/mL of blood or higher.

31. The method of any one of claims 21-30, wherein the agent is insulin.

32. The method of any one of claims 21-30, wherein the agent is an anti-inflammatory agent.

33. The method of claim 32, wherein the inflammatory agent is a cytokine inhibitor.

10017905 121401

34. The method of claim 32, wherein the inflammatory agent is a Tumor Necrosis Factor- α (TNF- α) inhibitor.

35. The method of claim 34, wherein the Tumor Necrosis Factor- α inhibitor is selected from the group consisting of Etanercept and Infliximab.

36. The method of any one of claims 21-30, wherein the agent is a hypoglycemic agent.

37. The method of any one of claims 21-30, wherein the agent is a lipid lowering agent.

38. A method for treating a subject to reduce the risk of diabetes or a diabetic complication, comprising selecting and administering to a subject in need of such treatment an agent for reducing the risk of diabetes in an amount effective to lower the risk of the subject developing diabetes or a diabetic complication, wherein the agent is selected from the group consisting of insulin, a hypoglycemic agent, an anti-inflammatory agent, a lipid lowering agent, a calcium channel blocker, a beta-adrenergic receptor blocker, a cyclooxygenase-2 inhibitor, and an angiotensin system inhibitor.

39. The method of claim 38, wherein the subject is otherwise free of symptoms calling for treatment with the agent.

40. The method of claim 38, wherein the subject is apparently healthy.

41. The method of claim 38, wherein the subject is nonhyperlipidemic.

42. The method of any one of claims 38-41, wherein the agent is insulin.

43. The method of any one of claims 38-41, wherein the agent is a hypoglycemic agent.

44. The method of any one of claims 38-41, wherein the agent is an anti-inflammatory agent.

10017905-121401

45. The method of claim 44, wherein the inflammatory agent is a cytokine inhibitor.

46. The method of claim 44, wherein the inflammatory agent is a Tumor Necrosis Factor- α (TNF- α) inhibitor.

47. The method of claim 46, wherein the Tumor Necrosis Factor- α inhibitor is selected from the group consisting of Etanercept and Infliximab.

48. The method of any one of claims 38-41, wherein the agent is a lipid lowering agent.

49. The method of any one of claims 38-41, wherein the agent is a calcium channel blocker.

50. The method of any one of claims 38-41, wherein the agent is a cyclooxygenase-2 inhibitor.

51. The method of any one of claims 38-41, wherein the agent is an angiotensin system inhibitor.

10017905-121401